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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/726,069
Filing Date: December 03, 2003
Appellant(s): KENTEN ET AL.

Gary R. Tanigawa
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12 February 2010 appealing from the Office action mailed 2 January 2009.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-4, 6-12, 14-19 and 21-29.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The subject matter of claims 26-29 has not been summarized specifically, i.e., apart from claim 25, from which they depend.

(6) Grounds of Rejection to be Reviewed on Appeal

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner: The rejection of claims 4, 5, 14, 21 and 22 under 35 U.S.C. §112, second paragraph.

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7, 21 and 22 stand rejected under 35 U.S.C. 102(b) as being anticipated by Gallatin et al. (US Patent 5,728,533, of record).

Gallatin et al. teaches, e.g., at column 5, second full paragraph, in a cell, a first construct comprising a reporter gene driven by a promoter, and a second DNA sequence from a library, wherein expression of the reporter gene is detected. A comparison to claim 1 to show each element is helpful, with the corresponding teachings of Gallatin et al. set forth in italics in the brackets:

Claim 1. A method for determining whether a gene product has an activity of interest [{the} "*assay may be used in isolating a polypeptide encoding a protein that binds to* α_d" at column 5, lines 38-40.]

comprising: (a) co-transfecting a cell with (i) a first vector selected from a library of vectors, at least two members of said library comprising genes which encode different test proteins, ["*expressing in the host cells a library of second hybrid DNA sequences encoding second fusions of part or all of putative* α_d *binding proteins and the DNA binding or activating domain of the transcription factor*"; column 5, lines 47-49.]

and (ii) a second vector comprising a gene which encodes a reporter protein, wherein said reporter protein affects or regulates a biological process in said cell; ["*transforming or transfecting appropriate host cells with a DNA construct comprising a reporter gene under the control of a promoter regulated by a transcription factor having a DNA-binding domain and an activating domain*"; column 5, lines 40-43.]

(b) expressing said different test proteins and said reporter protein in a transfected cell; (c) measuring abundance and/or activity of said reporter protein by observation of an indicator of said biological process in said transfected cell, wherein said abundance and/or activity of said reporter protein is modulated by the presence of a protein that modulates said reporter protein;

["*detecting binding of an α_d binding protein to α_d in a particular host cell by detecting the production of reporter gene product in the host cell*"; column 5, lines 51-53.];

and (d) screening said library for one or more members which encode test proteins that modulate said reporter protein. ["*and isolating second hybrid DNA sequences encoding α_d binding protein from the particular host cell*"; column 5, lines 53-55.]

At columns 47 and 48, Example 24, Gallatin et al. teaches an exemplary library of α_d, clones, containing 30,000 plaque forming units, i.e., per plate. At column 19, lines 19 and 30-33, co-transfection of COS cells is exemplified, using a transfection buffer also comprising the reagents DEAE-Dextran and chloroquine.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 4, 6, 8-12, 14-19 and 23-29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gallatin et al. (US Patent 5,728,533, of record) in view of Hillman et al. (US Patent 5,942,399, of record).

Gallatin et al. is described above. Gallatin et al differs from the claimed invention in not teaching specifically the recited transfection reagents, the use of luminescent, e.g., luciferase, or specifically-binding reporter gene products, or an apoptosis-related reporter gene, e.g., annexin, or repetition of the process to perform a negative control.

Hillman et al. teaches, e.g., at column 16, first full paragraph, the use of luciferase as a reporter gene. Also taught, e.g., at the paragraph bridging columns 16 and 17, is the detection of a protein produced from a gene of interest using an immunoassay or a competitive binding assay. At column 22, fourth full paragraph, Hillman et al. teaches that polycationic amino polymers may be used to transfect cells. At the paragraph bridging columns 36 and 37, Hillman et al. teaches the evaluation of the apoptotic state of transfected cells to identify them.

It would have been obvious to one of skill in the art to have practiced the screening method of Gallatin et al. employing any of the various selection methods set forth above, as taught by Hillman et al. The substitution of one known element (reporter gene, luciferase, taught by Hillman et al) for another (the reporter gene generically as set forth in Gallatin et al.), and another known element (the detection of a protein produced from a gene of interest using an immunoassay or a competitive binding assay, as taught by Hillman et al.) for another (detection of the reporter gene generically as set forth in Gallatin et al.), and another known element (the use of polycationic amino polymers to transfect cells, as taught by Hillman et al.) for another (use of the reagents DEAE-Dextran and chloroquine during transfection as taught by Gallatin et

al.), and another known element (the evaluation of the apoptotic state of transfected cells to identify them) for another (detection of the reporter gene generically as set forth in Gallatin et al.), would have been obvious to one of ordinary skill in the art at the time of the invention since the substitution of each of the features shown in Hillman et al. would have yielded predictable results, namely, detection of the reporter gene or detection of the transfection in the method taught by Gallatin et al. The use of a known reporter gene as a reporter in any desired construct would have been expected by one of skill in the art to have operated correctly. With respect to the use of negative controls, such are and were widely used in the prior art as a basic tool of scientific measurement and would have been expected to function in any experiment or assay procedure.

(10) Response to Argument

1. Response to arguments with respect to the rejection under 35 USC §102(b).

At page 9 of the Appeal Brief, Appellants argue that "the cited patent does not teach screening a *library* of vectors for one or more members that have a desired activity". However, as set forth in the Grounds of Rejection, above, a library is screened for isolating a polypeptide encoding a protein that binds to α_d, from a library of second hybrid DNA sequences encoding second fusions of part or all of putative α_d binding proteins and the DNA binding or activating domain of the transcription factor.

Further at page 9, and then at the paragraph bridging pages 11 and 12, Appellants argue that the cited patent does not teach the use of a reporter protein that affects or regulates a biological process in a cell. However, the claims merely require that the reporter gene be

expressed in the cell with the test protein, which it would be, as it is the same cell, and that the reporter protein affects or regulates a biological process in the cell, which it would do inherently, as the mere expression of the reporter protein itself would be a biological process. Furthermore, the mode by which the reporter protein is detected would itself involve a biological process, whether it be enzymatic activity by the reporter protein, or specific binding to the reporter protein, e.g., by an antibody. Appellants have not specified the nature of the biological process. With respect to modulation of the reporter protein by the test proteins, clearly the level of expression of the reporter protein is controlled by the expression of the test protein as part of the disclosed assay of Gallatin et al. No "speculation" has been employed, but merely the broadest reasonable construction of the claims.

At the top of page 11, Appellants argue that Gallatin et al. teaches transfection with one DNA construct, whereas the present invention requires two vectors, namely a first vector selected from a library of vectors and a second vector comprising a gene coding for a reporter protein. However, it is not apparent that Gallatin et al. teaches only a single vector. The two nucleic acid components are described separately, and no mention is made in Gallatin et al. of their presence on a common construct molecule.

Further at page 11, Appellants argue that the claimed invention requires the expression of different test proteins and the reporter protein in the transfected cell, whereas Gallatin et al. teaches two expression steps, namely expressing a first hybrid DNA sequence encoding a first fusion protein, followed by expressing a library of second hybrid molecules encoding a second fusion. However, Gallatin et al. also teaches expression of the reporter protein, and in view of the open language of the claim ("comprising"), the method taught by the patent is not excluded.

2. Response to arguments with respect to the rejection under 35 USC §103(a).

At the paragraph bridging pages 13 and 14, Appellants' criticisms of Gallatin et al. are reiterated, and accordingly are believed to have been addressed with respect to the rejection under 35 USC §102(b), above. It is also argued that Hillman et al fails to remedy the alleged defects of Gallatin et al. However, as it is maintained that Gallatin et al. is without these alleged defects, Hillman et al. is not required for this.

At page 14, Appellants argue that co-transfection occurs with a surprisingly high probability for two vectors. However, Gallatin et al. employed co-transfection, as set forth in the grounds of rejection under 35 USC §102(b), above, and as such, any unexpected success found by Appellants would have been found by Gallatin et al. Indeed, co-transfection is and was well-known in the art for this very reason.

At the first full paragraph at page 15, Appellants argue that the repetitive screening in multi-well plates would not have been obvious over the references. However, the mere repetition of a method for the purpose of continuing to process more starting material would have been obvious from simple logic. In a method of performing a useful task to achieve a desired outcome, it would be readily understood to all that one simply repeats the method if one wishes to repeat achieving the desired outcome.

Appellants' arguments at the second full paragraph at page 15 and in the paragraph bridging pages 15 and 16 are believed to have been addressed above, in the grounds of rejection and in the response to arguments.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/James Ketter/

Conferees:

/ Christopher S. F. Low /
Supervisory Patent Examiner, Art Unit 1636

/Bennett Celsa/
Primary Examiner